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Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	No. 2:15-MD-02641-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF ROBERT O. RITCHIE, PH.D, AND SUPPORTING MEMORANDUM OF LAW** (ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL) **(ORAL ARGUMENT REQUESTED)**

INTRODUCTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), respectfully move to exclude certain expert opinion testimony offered by Robert O. Ritchie, Ph.D. ("Dr. Ritchie"), a

professor of materials science and engineering. Bard's Motion is supported by the following Memorandum of Points and Authorities and any oral argument the Court may entertain.

MEMORANDUM OF POINTS AND AUTHORITIES

Bard seeks to exclude the following opinions of Dr. Ritchie:

1. Bard filters have "unacceptably high" complication rates;
2. One complication occurring in a Bard filter leads to other subsequent complications in a "vicious circle" of such events;
3. Bard's filter testing was insufficient; and
4. The Simon® Nitinol Filter is a safer, alternative product.

Bard seeks to exclude these opinions on the grounds that Dr. Ritchie is either not qualified to testify to these opinions, has failed to provide reliable, scientific methodology to support these opinions, and/or relies solely upon the work of other experts, without verification of that work by him. These opinions amount to unreliable, unsubstantiated conjecture that will not assist the trier-of-fact in determining the issues in this case.

ARGUMENT AND CITATION OF AUTHORITY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE DR. RITCHIE

For an expert's opinion to be admissible under Federal Rule of Evidence 702, the Court must find that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Rule 702 incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in which the Supreme Court charged trial courts with a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589. Ultimately, the objective of *Daubert* is "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The proponent of expert testimony must demonstrate admissibility by a

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preponderance of proof. *Daubert, 509 U.S.* at 592 n. 10; *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). And "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the above *Daubert* standard, the opinions discussed in this Motion are unreliable.

A fundamental requirement of Rule 702 is that the proposed scientific/technical testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." The Ninth Circuit has found that "[f]ederal judges *must* . . . *exclude* proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to [the] issue in dispute in the case, and that it will not mislead the jury." *Daubert v. Merrell Dow Pharms., Inc*., 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added).

The four opinions of Dr. Ritchie identified above will not assist the trier-of-fact and should be excluded. *See e.g., U.S. v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) (also noting that expert opinion is not helpful to the trier of fact "when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re: Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding testimony concerning regulatory history, FDA correspondence, and internal company documents, noting that the issues should be presented to the jury directly, not through an expert who "regurgitates them and reaches conclusory opinions . . . and invades the province of the jury."); *In re: Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007) (excluding testimony as "lay matters" and "conclusory statements about questions of fact masquerading behind a veneer of technical language" where plaintiffs proffered an expert to opine that Bayer ignored its toxicologists' concerns about Baycol's steep dose-response curve as it concerned Baycol's safety profile); *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on internal

documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand).

I. Dr. Ritchie is Not Qualified to Offer Rates-Related Opinions About Bard Filters.

When asked during his MDL deposition whether he is "going to testify about the relative rate of any given complication in any given Bard filter," Dr. Ritchie replied "No . . . I don't think I would – other people would do that better than I would . . ." (Ex. A, Ritchie Dep. Tr., 110:19-23, June 9, 2017.) However, in Dr. Ritchie's Rule 26 Reports, he opines that Bard filters have "high and unacceptable [complication] rate[s]" and "totally unacceptable failure rates," (Ex. B, Ritchie 3/2/17 Rule 26 Report, at 2, 45, 105), and "totally unacceptable fatigue failure rate[s]." (Ex. C, Ritchie 5/12/17 Rule 26 Rebuttal Report, at 5.)[1] He also testified that since fracture rates are "unacceptably high" other complications (tilt and perforation) are similarly "unacceptably high." (Ex. A, Ritchie Dep. Tr., 133:18-25, June 9, 2017.)

Dr. Ritchie is not qualified to provide opinions on Bard filter complication rates. Dr. Ritchie's fields of expertise are engineering, materials science, and fatigue failure. While in his Reports he refers vaguely to medical literature and Manufacturer and User Facility Device Experience ("MAUDE") data as alleged support for these opinions, Dr. Ritchie does not have the qualifications to analyze and draw conclusions about rates of complications in Bard filters from those, or any other, sources. He is not a biostatistician. (Ex. A, Ritchie Dep. Tr., 152:14-21, June 9, 2017.) He is not an epidemiologist. (Ex. D, Ritchie Dep. Tr., 69:11-13, May 23, 2011.) However, Dr. Ritchie references the report of plaintiffs' biostatistician -- Rebecca Betensky -- as an underlying foundation for his opinions on rates. (Ex. B, Ritchie 3/2/17 Rule 26 Report, at 3-4.) And in his MDL

[1] Bard does not argue that Dr. Ritchie should not be able to discuss his observations regarding the occurrence of fatigue failure and fractures in Bard filters; however, he should not be permitted to opine on "rates" or comparative rates of any Bard filter complications, or refer to them as "high and unacceptable" or "totally unacceptable," absent any foundation, expertise, or scientific methodology to support such opinions.

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deposition, he testified that he would defer to Dr. Betensky to provide the analysis of rates in these cases. (Ex. A, Ritchie Dep. Tr., 137:8 – 138:23, June 9, 2017.)

Courts have limited the scope of an expert's opinions where they venture into areas outside of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *See In re Silicone Breast Implants Litig.*, 318 F.Supp.2d 879, 902 (C.D.Cal. 2004) (excluding opinions about the defendant's failure to conduct tests proffered by the plaintiff's expert, who had worked in quality control for a pharmaceutical company, published papers about medical devices, and holds patents on medical devices, on the grounds that such experience is insufficient foundational knowledge for offering opinions on testing); *Kruger v. Johnson & Johnson Professional, Inc*., 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices); *In re: Breast Implant Litigation*, 11 F. Supp. 2d 1217, 1243-44 (D. Colo. 1998) (excluding design opinions of a scientist who held a Ph.D. in physical chemistry because being a chemist did not automatically qualify the witness on design issues when he lacked training and experience concerning design of breast implants).

Like the many courts that have excluded or limited the scope of opinions outside an expert's particular area of qualifications, the Court should exclude Dr. Ritchie's testimony about rates because he has no formal education, experience, training, or foundational knowledge to determine from any source what the "rates" are.

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II. Dr. Ritchie Employed No Scientific Methodology to Support His Opinion That Bard Filter Complication Rates Are "Unacceptably High".

Dr. Ritchie is neither able to identify what the rate of fracture (or any other complication) is in Bard filters, nor what makes those rates "unacceptably high." (Ex. A, Ritchie Dep. Tr., 131:14-140:18, June 9, 2017.)

He cannot articulate what sources he relies upon in reaching this opinion. (*Id*.) He vaguely refers to "medical studies" which he states provide some statistical analysis on this issue, and he points to the MAUDE database. (*Id*.) He agrees that he has not performed a complete study of medical literature to determine rates of complications, and he even notes that the MAUDE database is flawed. (*Id*.) He cites inaccurately and incompletely to the opinions of Plaintiff's biostatistician expert Dr. Betensky as support for his opinion[2], but agrees that he has done nothing to review or verify her analysis, and that he would defer to her with regard to Bard filter complication rates. (*Id*.)

Specifically, during his MDL deposition, Dr. Ritchie testified as follows regarding his opinions on "unacceptably high rates":

> Q. Alright. Then several lines down, you say: "Bard filters displayed an unacceptably high incidence of filter fractures."
>
> A. Uh-huh.
>
> . . .
>
> Q. What is -- what do you mean when you use the term, "unacceptably high" in this context?
>
> A. It's – it's -- I mean, we're talking about a device which has suffered a high percentage of fractures. I can't remember the numbers now, but in the studies I've looked at they've been pretty severe. And I think it's incumbent upon a medical device company to design something which

[2] Dr. Betensky does not opine in her report that Bard rates are "unacceptably high" relative to other retrievable filters. At most, her analysis was an attempt to show that Bard retrievable filters have a higher reporting risk ratio of complications than the SNF filter which is not a retrievable filter. (Ex. E, Betensky 1/27/17 Rule 26 Report, at 1-16.)

does not have such a large failure rate. I'm using the term loosely, but I think it's certainly -- if we were going to have one of those things put in and we saw the failure rates, to me, that would be an unacceptable failure rate.

Q. Okay. So who is it unacceptably high to? Are you saying from your perspective?

A. Of course, from my perspective, but I think anybody's perspective who looked at those numbers.

Q. Has the FDA said it's an unacceptably high rate?

. . .

THE DEPONENT: I don't know.

Q. (By Ms. Daly) How about the Society of Interventional Radiologists? Have they made any such statements?

. . .

THE DEPONENT: I don't know.

Q. (By Ms. Daly) Are you aware of any organization that's concluded that Bard filters have an unacceptably high incidence of any kind of complication? . . .

A. Offhand I can't say.

Q. When you used the term "unacceptably high incidence," were you speaking of as to fracture or any other type of complication for the Bard filters?

A. Well, I use the term "unacceptable fatigue failure rate," so I'm referring specifically there to the -- I mean, components that are put in the body should not fatigue, because that's – that's a very severe problem. And the -- the numbers -- the statistics of these, these fractures are particularly high. So in my terminology they're unacceptable.

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. . .

Q. Do you hold the opinion that there's any other complication in the Bard filter that is at the unacceptably high rate, in your opinion?

A. Well, again, it's a – it's a personal statement, but I think since -- since the fractures are all related to perforations, can be related to perforations and tilts and so forth, these filters were functioning in a situation that led to adverse events. These are documented in more data and so forth, so but I don't know who's -- whether the Society of Interventional Cardiologists have actually made comments on those; I've not read those, but I'd be surprised if they didn't.

Q. How are you -- how are you coming up with a determination of what the incidence of these various complications are in Bard in order for you to say they're unacceptably high?

A. Well, I've -- I mean, there's a whole set of data bases. I've looked at certain papers which have done smaller studies with numbers -- like 40 percent failures have been seen. That's obviously a small study. There's more data that has – there's -- what do they call it -- Labinski (sic) report or something?

Q. Betensky.

A. Betensky report -- that lists some of these things. These -- these -- these seem extremely high to me, and my understanding of general engineering, these are unacceptably high.

Q. What is the -- what is the study that you're talking about that's 40 percent rate of what?

A. Oh, there was -- some of the -- I remember having an interchange with Richard North about this, that some of the earlier studies that I list in here –

(Ex. A, Ritchie Dep. Tr., 131:14-134:25, June 9, 2017.)

Q. There were also a number of studies -- noticed you didn't cite any of them -- that had zero complication issues for Bard filters in those studies.

Q. (By Ms. Daly) So my point is -- my point is you didn't make a -- an exhaustive review of all studies of Bard filters to see what each one of them determined. Fair --

. . .

A. No, but, I mean, there has been studies on the statistics of adverse events in these devices, and I've certainly read about those, and it would be very hard to argue that the failure rate, particularly due to fracture of a Bard filter, was acceptable.

Q. What study is there that has done a statistical review of fracture in a Bard filter?

A. Well, there's -- there's the statistics of -- of -- I mean, there's – there's the MAUDE data that has the adverse events, right? There's a number of those statistics can be somewhat flawed, but they list the number of filters that have failed in a certain way, and there's the Barinsky (sic) report which has the statistics of different failure rates, so -- and I can't remember exactly the numbers of what those rates are offhand, but -- but

Q. You have not done a review to come up with a statistical analysis of rates of any complication with a Bard filter, fair?

A. I'm just looking at – I'm just reading people who have done those things.

Q. And really, Betensky, I think you're aware of Betensky is the expert for plaintiffs in this case who is a statistician; you know that?

A. Yes, of course.

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Q. Okay. Would you defer to her on her analysis of what the statistics show?

A. Well, she probably knows more about statistics than I do.

Q. So you would defer to her?

A. I guess I would, yes.

(Ex. A, Ritchie Dep. Tr., 137:8-138:23, June 9, 2017.)

Q. Let's talk a minute about Betensky, if we could. You did not really discuss her analysis in your report; you -- you

A. No, I don't.

. . .

Q. Have you ever discussed her analysis with her?

A. No.

Q. Have you read the Excel spreadsheets or reviewed the Excel spreadsheets that she created as part of that report?

A. I don't think I've gone in any detail, no.

Q. So I take it you have not undertaken to verify what her analysis was.

A. No.

(Ex. A, Ritchie Dep. Tr., 139:16-140:18, June 9, 2017.) Absent any specific, underlying data (which he was unable to cite), scientific methodology (which he has not undertaken), or independent verification of the work and conclusions of other experts (which he has not done), Dr. Ritchie's opinion on "unacceptably high" rates is speculative and should be excluded.

III. Dr. Ritchie's Opinion That One Complication Occurring in a Bard Filter Leads to Other Subsequent Complications in a "Vicious Circle" of Such Events Should be Excluded.

Dr. Ritchie opines that there is a "vicious circle" in Bard filters where one filter failure mode leads to others. (Ex. B, Ritchie 3/2/17 Rule 26 Report, at 36.) For example, a fracture can lead to filter tilt, which can promote filter perforation, which can lead to further fractures. (*Id*.) Dr. Ritchie admits that he cannot say with certainty the probability

of one failure mode causing another failure mode, but testified "[w]ell, there's statistics" he has read that show "probabilities of failure . . . based on postmortem effects of looking at these devices." (Ex. A, Ritchie Dep. Tr., 95:6:18-101:24, June 9, 2017.) But Dr. Ritchie was unable to cite to data, numbers, medical literature, or other materials providing these "statistics" which allegedly support this theory of a "vicious circle." (*Id*.) This does not does not meet *Daubert* standards.

Dr. Ritchie also employed no scientific method to support his opinions of "vicious circle." He cites to no medical study concluding that such "vicious circle" occurs, or the frequency with which it occurs. When asked in his deposition if this opinion amounts to a hypothesis, he simply responded that "there's certain things that are intuitively obvious to me." (*Id*. at 89: 2-11.) He admitted however that "whether tilt precedes migration or migration precedes tilt is . . . sort of almost an impossible question to answer." (Id. at 97: 8-10.)

The Rule 702 Advisory Committee states: "[t]he trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" *Id*. (citing *Daubert v. Merrell Dow Pharms. Inc.*, 43 F.3d 1311, 1315 (9th Cir.), cert. denied 516 U.S. 869, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995)). In addition, "any step that renders [the expert's] analysis unreliable ... renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." *In re Silicone Breast Implants Litigation*, 318 F.Supp.2d at 890 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir.1994)).

Dr. Ritchie refers to Dr. McMeeking's analysis in these cases as support for his own opinions on the "vicious circle." (Ex. A, Ritchie Dep. Tr., 84:1-91:8, June 9, 2017.) "[I]t's nice to get some . . . numerical confirmation [from Dr. McMeeking's analysis]." (*Id*. at 88:22-89:11.) However, Dr. Ritchie testified that he has not verified any of Dr. McMeeking's calculations, that he defers to Dr. McMeeking on the results of those and how they may support this theory. (*Id*. at 101:25-107:1.) Assuming that Dr. McMeeking's analysis is admissible, Dr. McMeeking, who performed the analysis, may testify to it.

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An expert's sole or primary reliance on the opinions of other experts raises serious reliability questions. *See Fosmire v. Progressive Max Ins. Co.*, 277 F.R.D. 625, 629 (W.D.Wash.2011) ("Dr. Polissar's expert report is deficient in several ways. First, although his opinions are based on Dr. Siskin's data and methodology, there is nothing in the record to indicate that Dr. Polissar has tested Dr. Siskin's underlying data to ensure its reliability or that Dr. Polissar even has access to Dr. Siskin's underlying data"); *In re Imperial Credit Indus., Inc. Securities Litig.*, 252 F.Supp.2d 1005, 1012 (C.D.Cal.2003) ("The rules do not permit an expert to rely upon excerpts from opinions developed by another expert for the purposes of litigation"); *see also American Key Corp. v. Cole Nat'l Corp.*, 762 F.2d 1569, 1580 (11th Cir.1985) ("Expert opinions ordinarily cannot be based upon the opinions of others whether those opinions are in evidence or not").

Dr. Ritchie's opinions on "vicious circle" add nothing to benefit the trier-of-fact since he can point only to various analyses performed by Dr. McMeeking which he has not verified, he cannot point to any reliable scientific method used by him in reaching those opinions, and he admits the only other basis for his opinion is his "intuition."

IV. Dr. Ritchie is Not Qualified to Criticize Bard's Testing.

In his Rule 26 Report, Dr. Ritchie criticizes Bard's testing, referring to it as "inadequate" or "totally inadequate." (Ex. B, Ritchie 3/2/17 Rule 26 Report, at 28, 31-33, 35, 45, 54, 57, and 87.) Dr. Ritchie testified that he reviewed various Bard testing documents and it was "obvious" to him that the testing was inadequate and did not simulate reality. (Ex. A, Ritchie Dep. Tr., at 116:21 – 120:15, June 9, 2017.) His basis for stating that Bard's testing is inadequate is the fact that some patients have experienced complications with Bard's filters. (*Id*. at 116:24-117:24; 119:10-120:9.)

Dr. Ritchie provides no engineering or scientific methodology to support his opinions that the Bard testing was insufficient. Dr. Ritchie testified that he has performed fatigue testing on "virtually every material on the planet," but admits that he has not attempted to fashion any protocols for testing he claims Bard should have performed. "Well, you know, no, that would not be my position, but I think they should have done

so." (*Id.* at 161:4-162:3.) He has not developed or performed tests which he can demonstrate would have been more adequate, (*Id.* at 36:20-37:8) or which would have better simulated the conditions he claims Bard was unable to simulate during its testing. (*Id*. at 118:15-120:9.) Having not done that work, he does not know what the results of different testing would have shown or what they would, or would not, have informed Bard about. Dr. Ritchie is essentially asking the trier-of-fact to "take his word for it" because he is an engineer who studies fatigue failure he can look at testing documents and conclude the tests were inadequate. As discussed above, the drafters of Rule 702 did not intend for courts and juries to rely on an expert's "word" without any objective, verifiable standard to support it.

V. Dr. Ritchie's Opinion That the Simon® Nitinol Filter is a Safer Alternative Product Should Be Excluded.

Dr. Ritchie testified that the Simon Nitinol Filter ("SNF"), the permanent IVC filter sold by Bard, is a safer alternative product to Bard retrievable filter models based on its alleged lower complications rates. (Ex. A, Ritchie Dep. Tr., 156:9-18, June 9, 2017.) As discussed previously, Dr. Ritchie is neither qualified to offer an opinion on what the rates are in Bard filters or in SNF filters, nor has he employed any scientific methodology to support the opinion. In support of this opinion, he admits he relies on Dr. Betensky's analysis, which he has not attempted to verify in any way, and then states that he defers to Dr. Betensky to explain her methodology and what her analysis shows, if anything, about the complication rates in Bard's retrievable filter models versus the SNF filter. (Ex. A, Ritchie Dep. Tr., 137:8-138:23, 139:16-140:18, June 9, 2017.)

Courts have held that where the purported safer alternative product is not the functional equivalent of the allegedly defective product it is not a safer alternative. *See e.g., McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) (finding that regular bullets were not a feasible alternative design for hollow-point bullets because the expansion mechanism of the hollow-point bullets "was an intentional and functional element of the design of the product."); *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d

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223, 247–48 (E.D.N.Y. 2014) (holding the plaintiff cannot satisfy his burden to propose a feasible alternative design by proposing that an entirely different product (trap saw) could have been used instead of the allegedly defective table saw, where the expert provided no evidence that the trap saw can make the same cuts as a table saw or even be used at a construction site); *Kass v. West Bend Co.*, No. 02 CV 3719, 2004 WL 2475606, at *6 (E.D.N.Y. Nov. 4, 2004) (holding that "courts have repeatedly rejected expert testimony where a proposed theory or alternative design was not properly tested for safety or utility"); *Felix v. Akzo Nobel Coatings*, 262 A.D.2d 447, 692 N.Y.S.2d 413 (2d Dept.1999) (holding the "functional difference" between an allegedly defective quick-drying, solvent-based lacquer and the plaintiff's purported safer alternative, a water-based lacquer taking hours to dry, was fatal to the plaintiff's safer alternative argument).

Even assuming that there will be evidence introduced in this case by some expert as to the complication "rates" in Bard filters, the mere fact that SNF filters may have fewer reported complications associated with it is not sufficient to support an opinion by Dr. Ritchie, or any other expert, that such comparative rates mean the SNF is a safer alternative product. Courts have rejected opinions similar to Dr. Ritchie's opinion that Bard filters are dangerous based on a perceived number of complications. *See e.g. Barban v. Rheem Textile Sys., Inc.*, No. 01 CV 8475, 2005 WL 387660, at *3-7 (E.D.N.Y. Feb. 11, 2005) (excluding expert testimony that the table saw in issue was inherently dangerous simply based on the number of injuries involving such table saws, where the expert had never designed any machines, never conducted studies or authored articles related to dry cleaning, undertook no utility studies, and offered no alternative designs.)

Dr. Ritchie admits that the SNF is a permanent filter, whereas, the other Bard filters are retrievable filters. (Ex. A, Ritchie Dep. Tr., 143:1-20, June 9, 2017.) While Bard retrievable filters may be implanted for permanent use, they also carry with them the important design characteristic of being able to be percutaneously retrieved. Given the functional difference between the SNF and Bard retrievable filter models, under the cited case law, the SNF cannot amount to a safer alternative product here. In addition, Dr.

Ritchie is not a medical doctor. (Ex. A, Ritchie Dep. Tr., 152:14-21, June 9, 2017.); (Ex. D, Ritchie Dep. Tr., 39:16-22, May 23, 2011.) Therefore, he is not qualified to offer the opinion that the SNF (a permanent filter that cannot be percutaneously retrieved) would be a safer alternative for any patient, and in particular for any of the five bellwether plaintiffs in this MDL. He cites to no testimony from any implanting doctor that the doctor selected a Bard retrievable filter for the patient without considering the retrievable function that accompanied the Bard filters.[3] Consequently, Dr. Ritchie is not qualified, and has not employed any reliable methodology, to determine that an SNF filter was a safer alternative product for any individual in this litigation.

CONCLUSION

Because Dr. Ritchie is unqualified to opine about the topics identified above, failed to use scientific methodology, and/or simply relied on opinions and analyses of other experts without verifying those opinions, his opinions are unreliable, will not help the jury determine the issues, and should be excluded.

DATED this 24th day of August, 2017.

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[3] Plaintiffs argue that in the case of Bellwether Plaintiff Carol Kruse, her implanter intended that the retrievable Bard filter he placed would be permanent in that patient, however, the implanter specifically testified that part of his consideration for use of the Bard filter in that patient was that it was retrievable in case it needed to be retrieved. (Ex. F, Smith Dep. Tr., 57:9-16; 68:16-20, April 4, 2017.)

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CERTIFICATE OF SERVICE

I hereby certify that August 24th 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.

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